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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,477	04/15/2004	Fabio Soldati	1/1490	8137
28501 7590 09/07/2007 MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/07/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,477

Applicant(s)

SOLDATI ET AL.

Examiner

Snigdha Maewall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 5-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>08/02/2007</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Summary

1. Receipt of IDS filed on 08/02/2007 is acknowledged. Receipt of Applicants Amendments and Arguments/Remarks filed 08/02/2007 is acknowledged.

Claims **1, 5, 7-8 and 10- 13** have been amended. Claims **3-4** have been cancelled in this Application. Accordingly, claims **1-2 and 5-20** are pending in this application and claims **1-2** and claims **5-20** will be prosecuted on the merits.

In view of Applicants Amendments, the 35 USC 112 and 35 USC 102 rejections have been withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2 and 5-9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of deVries et al. (US Patent No. 6,495,177 B1).

('777) discloses a composition comprising the following minerals and vitamins recommended for pregnant and lactating women: calcium, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, folic acid, niacin (page 2, paragraph 6 and claim 2). DHA is disclosed on (page 4, paragraph, 4). ('777) further discloses that the composition can be in the form of pill, capsule, tablet, chewable candies form (page 6, paragraph, 6). ('777) does not teach the specific weight ratios of various components as claimed. However, with respect to the weight ratios of various components, it is the examiners position that such a parameter is within the purview of a skilled artisan by doing experimental manipulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

('777) does not teach problems associated with calcium in chewable multi vitamin tablet. deVries teaches an orally administrable nutritional supplement which is highly palatable, such as a chewable prenatal vitamin/mineral supplement. The supplement is preferably made in the form of a tablet that, upon chewing, dissolves rapidly in the mouth. The tablet is particularly suitable for administration of vitamins and minerals to women during pregnancy. The invention also includes methods of making and using such supplements (abstract). The invention comprises vitamins, carotene, iron, flavorants etc. Calcium is excluded from the solid dosage form or if present is in less than therapeutic amount DeVries further teaches that preferred absence of calcium from the tablet ensures

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minimal interference of iron absorption by minerals present in the tablet. (see column 7, lines 5-53 and column 11, lines 28-35).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to exclude calcium from the composition forwarded by ('777) because deVries teaches that absence of calcium from the tablet ensures minimal interference of iron absorption by minerals. A skilled artisan would thus have been motivated to formulate a composition comprising vitamins and minerals as claimed in the instant invention with an expectation of obtaining a dietary composition which would supplement the needs of a pregnant women with a reasonable success.

4. Claims 10-13 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of de vries et al. (US Patent No. 6,495,177 B1) and further in view of Uiterwaal et al. (US patent No. 4,710,387). The teachings of ('777) and devries have been discussed above. ('777) and devries do not teach molybdenum, chromium and iodine in the composition.

Uiterwaal et al. teaches nutritional supplement preparation for pregnant and breast-feeding women based on milk constituents for pregnant and breast feeding women comprising iodine, calcium, phosphorus, various vitamins, chromium and molybdenum, niacin and folic acid etc. (see Table A in column 7, claim 5 and 8). Since the composition provides nutritional supplement to pregnant and breast feeding women, it would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate nutrients such as iodine, chromium and molybdenum

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in the composition forwarded by ('777). A skilled artisan would have made a formulation comprising molybdenum, chromium, iodine, vitamins, minerals, niacin, folic acid and DHA with a reasonable expectation of success.

With respect to the weight ratios of various components and amounts, it is the examiners position that such parameters are within the purview of a skilled artisan by doing experimental manipulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53777 ('777) in view of de vries et al. (US Patent No. 6,495,177 B1) and further in view of Uiterwaal et al. (US patent No. 4,710,387) and DRUGDEVELOPMENT AND INDUSTRIAL PHARMACY, 12(8&9), 1133-1144 (1986) Robert F. Jimerson.

The teachings of ('777), devries and Uiterwaal et al. have been discussed above. The references do not teach oblong gelatin capsule. However, Robert F. Jimerson discloses soft gelatin capsule. Robert F. Jimerson further disclose that because of their special properties and advantages, soft gelatin capsules are employed for a wide variety of uses in pharmaceutical industries and are produced in a variety of shapes, sizes, and colors. Their current applications primarily include, oral dosage forms, suppositories and topical products (see page 1134, paragraph 2 and 3).

It would have been obvious to the one of ordinary skilled in the art at the time the

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invention was made to make gelatin capsule of the oblong shape since the article teaches that gelatin capsules bear special properties and advantages in pharmaceutical compositions. A skilled artisan would have made gelatin capsule comprising various nutritional components comprising vitamins, minerals, folic acid, biotin and niacinamide with a reasonable expectation of success.

Response to Arguments

6. Applicant's arguments with respect to claims 1-2 and 5-20 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

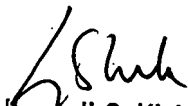
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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